EXHIBIT 4

From: Mahar, Kevin [ETHUS]
Sent: Sun, 28 Oct 2007 21:20:02 GMT
To: Foltyn, Ted [ETHUS] <TFoltyn1@ETHUS.JNJ.com>
Subject: FW: TVT O versus TVT Secur efficacy and safety rates

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Hello Ted, can we meet live - would like to get your thoughts/direction on all this - also, would like to know if you are planning to review with Renee - maybe we can speak tomorrow at the WLI?

Thanks,
Kevin

-----Original Message-----
From: Khoo, Teng Chuan. Dr. [MEDAP]
Sent: Thursday, October 25, 2007 5:22 AM
To: Robinson, David [ETHUS]; MAREE, Aran [MEDAU]; Megan, Joseph [MEDAP]; Yelisetti, Sateesh [JNJINMH]
Cc: GRIEBEL, Paul [MEDAU]; HARKNESS, Darryl [MEDAU]; Mahar, Kevin [ETHUS]; Foltyn, Ted [ETHUS]; Smith, Dan [ETHUS]
Subject: Re: TVT O versus TVT Secur efficacy and safety rates

David, that would be important adjunctive information for us to review.

Regards, Dr TC Khoo
Via BlackBerry

-----Original Message-----
From: Robinson, David [ETHUS]
To: MAREE, Aran [MEDAU]; Khoo, Teng Chuan. Dr. [MEDAP]; Megan, Joseph [MEDAP]; Yelisetti, Sateesh [JNJINMH]
CC: GRIEBEL, Paul [MEDAU]; HARKNESS, Darryl [MEDAU]; Mahar, Kevin [ETHUS]; Foltyn, Ted [ETHUS]; Smith, Dan [ETHUS]
Sent: Thu Oct 25 17:14:04 2007
Subject: Re: TVT O versus TVT Secur efficacy and safety rates

Joe
I would suggest you contact Joy Hovsepian (now de Los Reyes) to get the outcome document from the recent US proctors meeting. This detailed their thoughts re: training and surgical techniques.
Dave
David Robinson, M.D., F.A.C.O.G.
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----- Original Message -----
From: MAREE, Aran [MEDAU]
To: Khoo, Teng Chuan. Dr. [MEDAP]; Robinson, David [ETHUS]; Megan, Joseph [MEDAP]; Yelisetti, Sateesh [JNJINMH]
Cc: GRIEBEL, Paul [MEDAU]; HARKNESS, Darryl [MEDAU]; Mahar, Kevin [ETHUS]; Foltyn, Ted [ETHUS]; Smith, Dan [ETHUS]
Sent: Thu Oct 25 05:00:36 2007
Subject: Re: TVT O versus TVT Secur efficacy and safety rates

Thanks, TC and David.

A call would be good to discuss further: I am keen to learn what constitutes best practice in terms of deployment/insertion of this device and how that contrasts with what our docs are doing here. What constitutes best practice training and what have our docs received here? I am also keen to learn of any high quality case series with formally documented follow-up achieving a high success rate in terms of sustained continence with this device.

While I do not want to appear unnecessarily negative about what I am sure is a well-designed and innovative product, I know that the Australian regulator, with whom I regularly discuss our adverse events, may well suggest that this device may be more successful on the drawing board than in reality because the average practitioner finds it too complicated to insert correctly or cannot master the process. In this case, if some surgeons cannot achieve competency early on, we should restrict access to those who can. We may need to be able to convince them that we can improve outcomes to remain on the market.

Regards,

Aran

-----Original Message-----
From: Khoo, Teng Chuan. Dr. [MEDAP]
To: Robinson, David [ETHUS]; Megan, Joseph [MEDAP]; MAREE, Aran [MEDAU]; Yelisetti, Sateesh [JNJINMH]
CC: GRIEBEL, Paul [MEDAU]; HARKNESS, Darryl [MEDAU]; Mahar, Kevin [ETHUS]; Foltyn, Ted [ETHUS]; Smith, Dan [ETHUS]
Sent: Thu Oct 25 18:45:54 2007
Subject: Re: TVT O versus TVT Secur efficacy and safety rates

David, there has been a suspicion that some of these outcomes are related to operator based technique

deployment as you mentioned.

On a parallel route, we wanted to eliminate any possibility of product related issues while considering the adequacy of training and what is needed to properly rollout a device such that patients receiving them do not get the short end of the stick. The responsibility of controlling the adequacy of training is critical and this has also been the subject of discussion between Aran and myself.

I would suggest that the QA folks be allowed their due diligence while we explore and discuss further what can be done to adequately address the possibility of the technique related area of concern.

Aran, perhaps a teleconference with David will bring us to next steps.

Regards, Dr TC Khoo
Via BlackBerry

-----Original Message-----
From: Robinson, David [ETHUS]
To: Megan, Joseph [MEDAP]; Khoo, Teng Chuan. Dr. [MEDAP]; MAREE, Aran [MEDAU]; Yelisetti, Sateesh [JNJINMH]
CC: GRIEBEL, Paul [MEDAU]; HARKNESS, Darryl [MEDAU]; Mahar, Kevin [ETHUS]; Foltyn, Ted [ETHUS]; Smith, Dan [ETHUS]
Sent: Thu Oct 25 16:20:16 2007
Subject: RE: TVT O versus TVT Secur efficacy and safety rates

Joe and All
The differences in success seen by various users across continents is difficult to understand. Since Secur clearly is a sling "unto itself" as far as techniques go, much relearning had to occur to gain success in the US and particularly in Europe. Based on the success seen following adoption of those relearnings, it appears this is a technique issue rather than an inherent defect in the device itself.
As you know, Dan Smith and I had to make several trips to Europe to meet with docs having early failures and revise their technique. When Dan actually went into ORs and watched docs do cases, what he found was that what they told us they were doing and what they were actually doing were two different things. I do not know if you want to consider a similar trip to APAC for him (or another proctor having success if Dan is not allowed that much time out of R&D activities)but that may be what is needed, as it was in Europe.
Be glad to discuss further.
Dave

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-----Original Message-----
From: Megan, Joseph [MEDAP]
Sent: Thursday, October 25, 2007 1:15 AM
To: Khoo, Teng Chuan. Dr. [MEDAP]; MAREE, Aran [MEDAU]; Yelisetti, Sateesh [JNJINMH]
Cc: Robinson, David [ETHUS]; GRIEBEL, Paul [MEDAU]; HARKNESS, Darryl [MEDAU]
Subject: RE: TVT O versus TVT Secur efficacy and safety rates

Dear TC, Sateesh, and Aran,

Thank you for keeping me informed re the below.

Aran - If you have not already, I suggest a conversation with Dr David Robinson who is our WW Medical Director, based in NJ (I have copied Dave above). I am more than happy to set-up and join this discussion.

TC - Perhaps you and I can have a quick conversation in person. I am back in Singapore tomorrow (Fri) but I believe at a conference most of the day, but of course have time for this important issue. I am also in Singapore all next week.

I look forward to hearing from you regarding how I can help us best address the questions on SECUR, with our Credo approach.

Best regards,

Joe

-----Original Message-----
From: Khoo, Teng Chuan. Dr. [MEDAP]
Sent: Thursday, 25 October 2007 8:04 AM
To: MAREE, Aran [MEDAU]; Yelisetti, Sateesh [JNJINMH]
Cc: PENSABENE, Tony [MEDNZ]; CAPPLIS, Anne [MEDAU]; HARKNESS, Darryl [MEDAU]; Megan, Joseph [MEDAP]; SCHERINI, Robert [MEDAU]; GRIEBEL, Paul [MEDAU]
Subject: Re: TVT O versus TVT Secur efficacy and safety rates

Thanks for dropping this note Aran.

For some clarity and so that we are sure that we are talking about the same things, could you let us have your definition of "failure" and whether this occurs in the immediate post op, acute/subacute or as a longer term complication. A tablulated result or at least some estimate will be useful.

Sateesh, let's get together on this and if it makes sense, let's see if we can grab Ken Sumner while he is here in Chengdu to brief and discuss with him as well.

Joe, I'd like your input on this issue as well and to understand what the experience is on a regional basis. Sateesh, we need some hard numbers on this complaint as well if we can get them. I want to be able to see if this is an Australia only issue or a larger one.

As it involves patients, let's put some priority into actions related to this discussion.

Regards, Dr TC Khoo
Via BlackBerry

-----Original Message-----
From: MAREE, Aran [MEDAU]
To: Khoo, Teng Chuan. Dr. [MEDAP]; Yelisetti, Sateesh [JNJINMH]
CC: PENSABENE, Tony [MEDNZ]; CAPPLIS, Anne [MEDAU]; HARKNESS, Darryl [MEDAU]; Megan, Joseph [MEDAP]; SCHERINI, Robert [MEDAU]; GRIEBEL, Paul [MEDAU]
Sent: Thu Oct 25 07:50:55 2007
Subject: TVT O versus TVT Secur efficacy and safety rates

Dear TC & Sateesh,

Following on from my regular Medical Affairs update with TC in which I briefed you on matters pertaining to Medical Affairs in Australia and NZ, I want to just reiterate my concerns regarding the high 'failure' rates across multiple centres that we are seeing with TVT-Secur when compared to its predecessor TVT-O. I feel that you should be aware of our issues with TVT Secur for your surveillance in other AP countries and in case there are aspects on which you may have any further advice for me. While we launched in Australia just under 12 months ago, we have not yet launched this product in New Zealand.

By way of general background, we have multiple surgeons (~20) who have been trained in this procedure but only 3 with significant patient cohorts at this stage:

Prof Malcolm Frazer Performed: ~ 20 cases Failure: ~13 cases (he has performed about 700 TVT cases over the years)
Dr Bruce Farnsworth Performed: ~ 30 cases Failure: ~6 cases
Prof Marcus Carey Performed: ~ 20 cases Failure: "lots of early failures", awaiting a number from this surgeon

Prof Carey trained with Dr Vince Lucente in the USA and subsequently was involved in training the other two surgeons. I have had uncorroborated verbal feedback only to the effect that Dr Lucente has subsequently had to modify his technique from the original training to improve his results somewhat but that his 'failure rate' may still be higher than with TVT-O. Apparently Prof Frazer has taken on board Dr Lucente's 'modified technique' but is not experiencing a substantial improvement in success rates. Again, only verbal feedback, but I need to take this into consideration.

My concerns are the following:

(1) This product may have been launched as a substitute for TVT-O without enough clinical data to justify such a roll-out.
(2) TVT-O may rather be a product with a niche application in some patients for whom TVT-O is a less attractive option, after full disclosure of the higher failure rates observed with this product.
(3) The original (and current?) training program may not result in competency in device insertion or result in clinical efficacy. There appear to be "tricks" to insertion of the product and removal of the inserters which

prevent dislodging the device in the process etc.
(4) As a company we need to ensure that we protect the good name of J&J reputation and avoid such issues going forward elsewhere with this product and with other products.

Our QA team is reporting these complaints through correct channels to Gynecare and will also have to make a report to the TGA locally (Australian regulator) since 3 patients (so far)have required re-operation at this stage. once we get more data we will review the root cause locally and with Gynecare and will need to develop an action plan. I may well have to go and meet with the regulator as we get more data, as part of our legislated post-market surveillance responsibilities, and discuss the possible root-cause and a remedial action plan. A similar recent issue with the DePuy ASR prosthesis resulted in an international Safety Alert notice being issued jointly with the TGA through the GHTF member agencies (US, Europe etc).

This issue, as well as the DePuy ASR issue, are reminders to me that of our first Credo responsibility to ensure that we are diligent as a company in performing an adequate pre-market assessment on multiple dimensions before launching a new product. In ANZ we are currently revisiting our formal 'New Product Introduction' process, and we will be building in a formal pre-market risk assessment and post-launch market surveillance plan for certain new products. We will also need to check that new products, when either significantly modified from predecessors or which bring with them a substantially new technique, have adequate pre-market safety and efficacy clinical data to justify their launch. Otherwise we will merely force our regulator and others to require a higher level of clinical evidence for every new product, even where arguably not justified.

I will keep you updated as to how this matter progresses.

Kind regards,

Aran

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